DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2005

Mr. L.G. Chandrasekhar
Managing Director
Sutures India Private Limited
472 D, 13th Cross, 4th Phase
Peenya Industrial Area,
Bangalore 560058, India

Re: K041515
Trade/Device Name: TRUGLYDE Absorbable Polyglycolic Acid Surgical Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(glycolide/L-lactide) Surgical Suture
Regulatory Class: II
Product Code: GAM
Dated: March 17, 2005
Received: March 21, 2005

Dear Mr. Chandrasekhar:

This letter corrects our substantially equivalent letter of April 8, 2005 regarding the trade name.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 *or* (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041515

Device Name: TRUGLYDE Absorbable Polyglycolic Acid Surgical Suture

Indications For Use:
TRUGLYDE Absorbable Polyglycolic Acid Surgical Suture is indicated for use in soft tissue approximation, including use in ophthalmic surgery, but not for use in cardiovascular and neurological procedures

Prescription Use ___x____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
Neurological Devices

K041515

APR 8 2005

SUTURES INDIA PVT.LTD

SUBMISSION OF PREMARKET NOTIFICATION (510K) FOR
ABSORBABLE POLYGLYCOLIC ACID SUTURE

SECTION NO: 17	PAGE NO: -17-1

K041515

510K SUMMARY as required by: 21CFR 807.92

A. APPLICANT INFORMATION

Name : SUTURES INDIA PVT. LTD

Address : 472 D 13 th Cross, 4 th Phase,
Peenya Industrial Area,
Bangalore–560058. India

PHONE NO. : 91-80-51272102 / 51272103 / 51272104

FAX NO. : 91-80-51171056

E mail : sutures@vsnl.com

Web Address : www.suturesin com

B. Contact Person : L.G.Chandrasekhar

: MANAGING DIRECTOR

C. Date Prepared : May 15,2004

D. DEVICE TRADE NAME

- Trade Name : TRUGLYDE
- Common name : Absorbable Surgical Suture,Synthetic (Polyglycolic Acid)
- Classification Name: Absorbable (poly glycolic acid) suture

E. PREDICATE DEVICES

- Maxon Absorbable Polyglycolic acid Suture, 510(k) Number K990951, United States Surgical Corporation, Norwalk, CT 06856
- Surgisorb PGA absorbable suture, 510(k) Number K984374. Samyang Corporation , Seoul, Korea.